CASE CV0330 NP

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John M. Kilcoyne	John M. Kilcoyne	July 28, 2004
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

WILD et al

APPLICATION NO: 10/811,014

FILED: MARCH 26, 2004

FOR: COMPRESSION DEVICE FOR THE LIMB

Art Unit: 3764

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF CERTIFIED COPY

Sir:

Attached please find the certified copy of the foreign application from which priority is claimed for this case:

Country:	United Kingdom
Application No.:	0307097.6
Filing Date:	March 27, 2003

Respectfully submitted,

John M. Kilcoyne
Attorney for Applicant
Reg. No. 33,100

Bristol-Myers Squibb Company
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Date: July 28, 2004

Patents Form 1/77

Patents Act 1977
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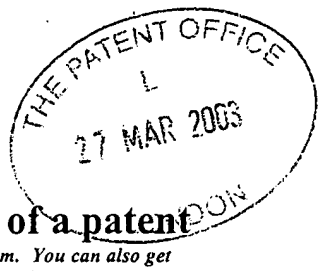

The **Patent Office**

1/77

28MAR03 E795778-1 D02806
P01/7700 0.00-0307097.6

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet, from the Patent Office to help you fill in this form)

The Patent Office

Cardiff Road
Newport
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1.	Your reference	JMCV0330.GB
2.	Patent application number *(The Patent Office will fill in this part)*	0307097.6 — 27 MAR 2003
3.	Full name, address and postcode of the or of each applicant *(underline all surnames)*	Bristol-Myers Squibb Company 345 Park Avenue New York NY 10154 United States of America (US)
	Patents ADP number *(if you know it)*	7579907001
	If the applicant is a corporate body, give the country/state of its incorporation	New York, United States of America
4.	Title of the invention	COMPRESSION DEVICE FOR THE LIMB
5.	Name of your agent *(if you have one)*	Barker Brettell
	"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*	10-12 Priests Bridge LONDON SW15 5JE
	Patents ADP number *(if you know it)*	7442494003

CERTIFIED COPY OF PRIORITY DOCUMENT

6.	If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number	Country	Priority application number *(if you know it)*	Date of Filing *(day/month/year)*

7.	If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application	Number of earlier application	Date of filing *(day/month/year)*

8.	Is a statement of inventorship and of right to grant of a patent required in support of this request *(Answer 'Yes' if:* *a) any applicant named in part 3 is not an inventor, or* *b) there is an inventor who is not named as an applicant, or* *c) any named applicant is a corporate body.* *See note (d))*	Yes

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9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	0
Description	7
Claim(s)	2
Abstract	DL
Drawing(s)	3+3

10. If you are also filing any of the following, state how many against each item.

Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination *(Patents Form 9/77)*	1 ✓
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature Julie Mays — Date 27 March 2003

Barker Brettell

12. Name and daytime telephone number of person to contact in the United Kingdom — Julie Mays — Tel: 020 8392 2234

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Signed Andrea Gray

Dated 24 March 2004

COMPRESSION DEVICE FOR THE LIMB

This invention relates to a compression device for the limb and particularly to a device for use on the leg. The device is particularly suited for use in the type of compression therapy used in the treatment of venous leg ulcers.

Various compression devices are known for applying compressive pressure to a patient's limb. These types of devices are used to assist mainly in the prevention of deep vein thrombosis (DVT), vascular disorders and the reduction of oedema. Prior art devices are adapted for use in a hospital setting in which they are used predominantly for the prevention of DVT in patients with a high risk for developing the same. US 5117812, US 5022387 and US 5263473 (The Kendall Company), US 6231532 (Tyco International Inc), US 6440093 (McEwen et al) and US 6463934(Aircast Inc) disclose such devices.

Compression therapy is used in the treatment of venous leg ulcers. The treatment relies on the compression achieving a reduction in oedema and improved return of blood via the venous system. This in turn reduces the residence time for blood supplied to the lower limb and the severity of ischaemic episodes within the limb that can result in tissue breakdown.

Compression of the limb in the treatment of venous leg ulcers is most usually achieved by the use of elastic bandages. Elastic bandages have the advantages that the patient can be mobile, can be treated at home and that once applied by a health care professional any removal or interference is easily detected. Elastic bandages do however have many disadvantages. They can work loose, the pressure generated by the bandage on the limb is not measured and depends on the level of skill of the health care professional applying the bandage, the level of

compression depends on the circumference of the limb, the bandage cannot be removed and reapplied by the patient, for instance for bathing, and many patients find them unsightly, uncomfortable, hot or painful.

Compression of the limb in the treatment of venous leg ulcers can also be achieved by the use of compression stockings, although they are most often used in the prevention of leg ulcers for instance in the prevention of recurrence after an active leg ulcer has healed. Compression stockings have many of the advantages of elastic bandages, they can be used at home and the patient can be mobile. They however have some disadvantages. They are difficult to apply as the narrow ankle part has to be pulled over the heel, compliance with treatment is difficult to monitor as the patient may be able to remove and replace the stocking themselves and patients can find them uncomfortable.

Compression of the limb can also be achieved by a pneumatic compression device. As explained above, known devices are predominantly used in the treatment of DVT where the patient is immobile and in hospital and as a consequence the devices are not adapted to the different needs of the venous leg ulcer patient. As venous leg ulcers are most usually treated at home or in the community and the known compression devices are large, heavy and require professional supervision, their adoption for such treatment has not been widespread. In addition most pneumatic compression devices require mains power which severely restricts patient mobility. This is undesirable and unnecessary. Further because the known compression devices are designed to be used on an immobile patient, they are not adapted to the challenges of a mobile patient who stands, walks, sits or lies down and thereby affects the pressure in the device. The known devices apply pressure to the limb through a thick cuff or cuffs which affect patient mobility and are aesthetically unacceptable to many patients. The pump

which produces the compression is large and heavy and can supply fluid to the cuffs through many pipes. These characteristics make the known devices unsuitable for domestic use. .

Pneumatic compression devices do however have advantages. They provide an effective treatment, while deflated, the inflatable cuff or cuffs are easy to apply to the patient's leg and the pressure is more readily controlled and monitored.

There thus exists a need for a device for use in the treatment of venous leg ulcers that overcomes the disadvantages of elastic bandages or stockings, that has the advantages of pneumatic compression but not the disadvantages of the known pneumatic devices. A small, ambulant, portable device is thus needed.

We have now invented a device for applying compressive pressures against a patient's limb which alleviates the above problems by providing a low profile, portable device which is simple to apply to the limb and is small and lightweight. A first aspect of the present invention provides a compression device for the limb comprising:
an inflatable sleeve adapted to surround the limb
a conduit attached to the sleeve for delivering fluid to the sleevc and a
a portable, wearable controller attached to the conduit that generates and controls the flow of fluid in the device.

We have found that such a device brings the advantages of pneumatic compression to leg ulcer patients.

Preferably the controller comprises a microprocessor control system and a pump. More preferably the device comprises at least one pressure sensor attached to the sleeve and located between the sleeve and the limb, the

sensors providing readings of the pressure experienced by the limb due to the inflation of the sleeve by the controller.

We have found that monitoring the actual pressure experienced by the limb due to the device enables the device to provide a predetermined compression profile to the limb. The predetermined compression profile may be selected by the health care professional to cater for the patient's condition. For example, a patient with lymphodema requires a higher level of compression than a patient with a healed leg ulcer. The sensor also allows the device to increase or decrease the pressure on a particular part of the limb to give the predetermined compression profile while the device is in use. This alleviates the problem of pressure difference experienced with the use of elastic bandages where the pressure depends on the tension in the bandage, the amount of overlap and the shape of the leg of the patient.

Preferably the sleeve comprises one or more individually inflatable cells. More preferably a sensor is associated with each cell to monitor the pressure experienced by the limb due to pressure from that cell. This allows the device to precisely control the pressure in each cell and thus comply with the predetermined compression profile. It also allows the device to operate a peristaltic compression.

The provision of individual cells in the sleeve and sensors that constantly monitor pressure at the inner surface of the sleeve between the sleeve and the limb, allow the device to be dynamic in that the controller can detect when a patient is standing and then sits or is sitting and then stands and walks. The level of compression that is required is higher when the patient is standing rather than sitting because of the effect of gravity which increases venous pressure in the limb. Thus when the patient stands, the controller inflates the sleeve to achieve the preset compression

profile on the limb. An advantage of this dynamic feature of the device is that the effectiveness of venous return is maintained whatever the patient does.

Due to the sensors and monitoring capacity of the device and the microprocessor present in the controller, it is possible to monitor the usage of the device by the patient. This is not possible with elastic compression devices. Knowledge of the extent of usage will enable the health care professional to prescribe the most suitable treatment for the next stage of healing or prevention.

The capability of the controller to deliver predetermined compression profiles to the limb also enables the health care professional to give the patient some control over their treatment. For a chosen treatment regime the patient can select a high compression or low compression setting. This alleviates the problem of non-compliance in some patients who cannot tolerate the pain of compression bandages or stockings that only provide one compression level. The use of the device on a low setting is preferable to rejection of the treatment altogether.

Preferably the sleeve is low profile and discrete. This allows the patient to use the device wearing ordinary clothes and shoes.

Preferably the sleeve comprises a leg cuff and a foot cuff both of which are low profile and discrete. More preferably the leg and foot cuffs are anatomically shaped to provide compression on those parts of the leg or foot which have the greatest effect on blood flow. This gives the advantage of reducing the overall size of the device and thus the profile of the cuff and size and power of the pump. Depending on the shape of the cuffs it can also reduce discomfort from pressure on bony areas of the limb.

Preferred embodiments of the invention will now be described with reference to the accompanying drawings in which:

Figure 1 is a perspective view of the sleeve of the device on the limb and the controller,

Figure 2 is a perspective view of the sleeve of the device off the limb and opened up and

Figure 3 is a perspective view of the sleeve and controller of a second embodiment of the device on the limb.

In Figure 1 the compression device of the invention is shown on the leg of a patient in a standing position. The device comprises a sleeve 2 having a leg cuff 4 connected to a foot cuff 6. The sleeve 2 is connected to a controller 8 by a conduit 10. The controller is a small, hand held unit that may be clipped to the sleeve or to the waistband of the patient's trousers or skirt. The controller is battery powered and rechargeable so that it can be recharged on the base unit 12. The device also comprises an understocking 14 worn between the patient's leg and the sleeve 2. The understocking is present to absorb any moisture from the patient's leg but does not apply compression. The sleeve 2 has an inner 16 and an outer 18 surface composed of a durable flexible material that can be sponged clean and is divided into a plurality of cells 20 best seen in Figure 2.

Figure 3 shows an alternative embodiment of the device of the invention where the leg cuff and foot cuff comprise cells with an anatomical shape 22. Each cell is provided with a sensor located centrally in each cell but on the inside of the sleeve between the sleeve and the leg. In Figure 3 the sleeve is marked on the outside at a position corresponding to the

position of the sensor in the inside of the sleeve at 24. The foot cuff in either embodiment may have a sensor located in a position corresponding to the instep of the foot.

As can be seen in both embodiments of the device, the patient puts the sleeve on by wrapping the leg cuff and the foot cuff around the leg or foot and securing them at the front of the limb where it is most bony. In this way pressure is applied by the sleeve where it is most needed, ie not on the bony areas of the limb but over the muscles.

Although the present invention has been shown and described with respect to several preferred embodiments thereof, various changes, omissions and additions to the form and detail thereof, may be made therein, without departing from the spirit and scope of the invention.

Claims

1) A first aspect of the present invention provides a compression device for the limb of a mobile patient comprising:
an inflatable sleeve adapted to surround the limb
a conduit attached to the sleeve for delivering fluid to the sleeve and
a portable, wearable controller attached to the conduit that generates and controls the flow of fluid in the device.

2) A compression device as claimed in claim 1 characterised in that the controller comprises a microprocessor control system and a pump.

3) A compression device as claimed in claim 1 or claim 2 characterised in that the device comprises at least one pressure sensor located between the sleeve and the limb.

4) A compression device as claimed in any preceding claim characterised in that the sleeve comprises one or more individually inflatable cells.

5) A compression device as claimed in any preceding claim characterised in that the sleeve is low profile and discrete.

6) A compression device as claimed in any preceding claim characterised in that the sleeve comprises a leg cuff and a foot cuff.

7) A compression device as claimed in any preceding claim characterised in that the leg and foot cuffs are anatomically shaped to provide compression on those parts of the leg or foot which have the greatest effect on blood flow.

8) A compression device as claimed in any preceding claim characterised in that the device further comprises an understocking interposed between the sleeve and the limb.

9) A compression device as claimed in claim 3 characterised in that the sensor or sensors are located on the inner surface of the sleeve.

10) A compression device as claimed in any preceding claim characterised in that the controller is battery operated.

11) A compression device as claimed in claim 4 characterised in that each cell is monitored by a sensor.

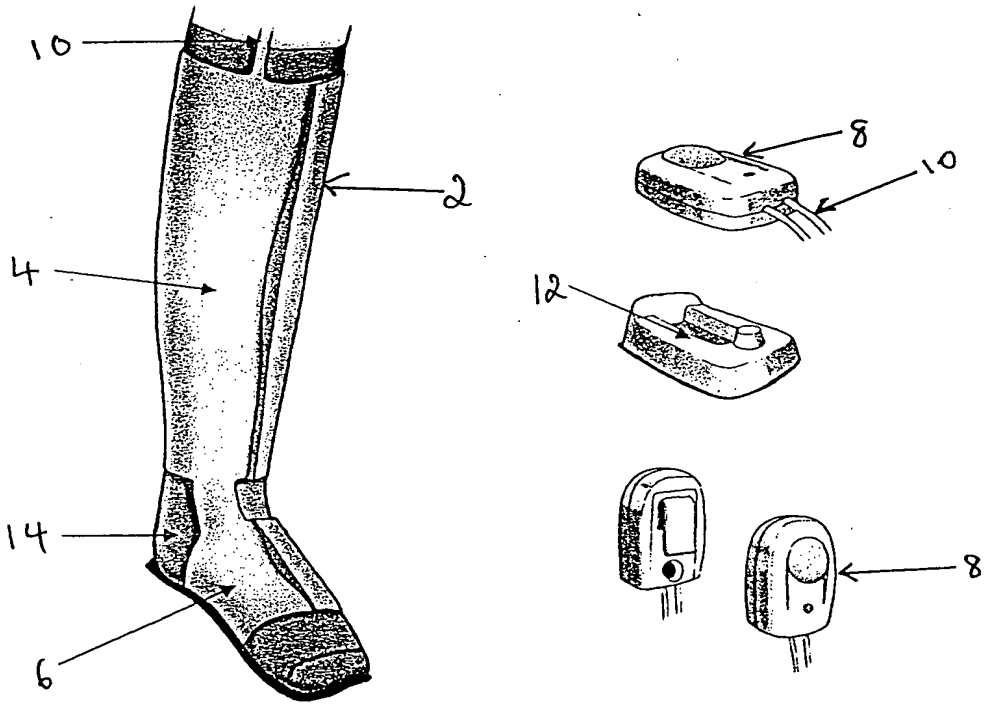

Figure 1

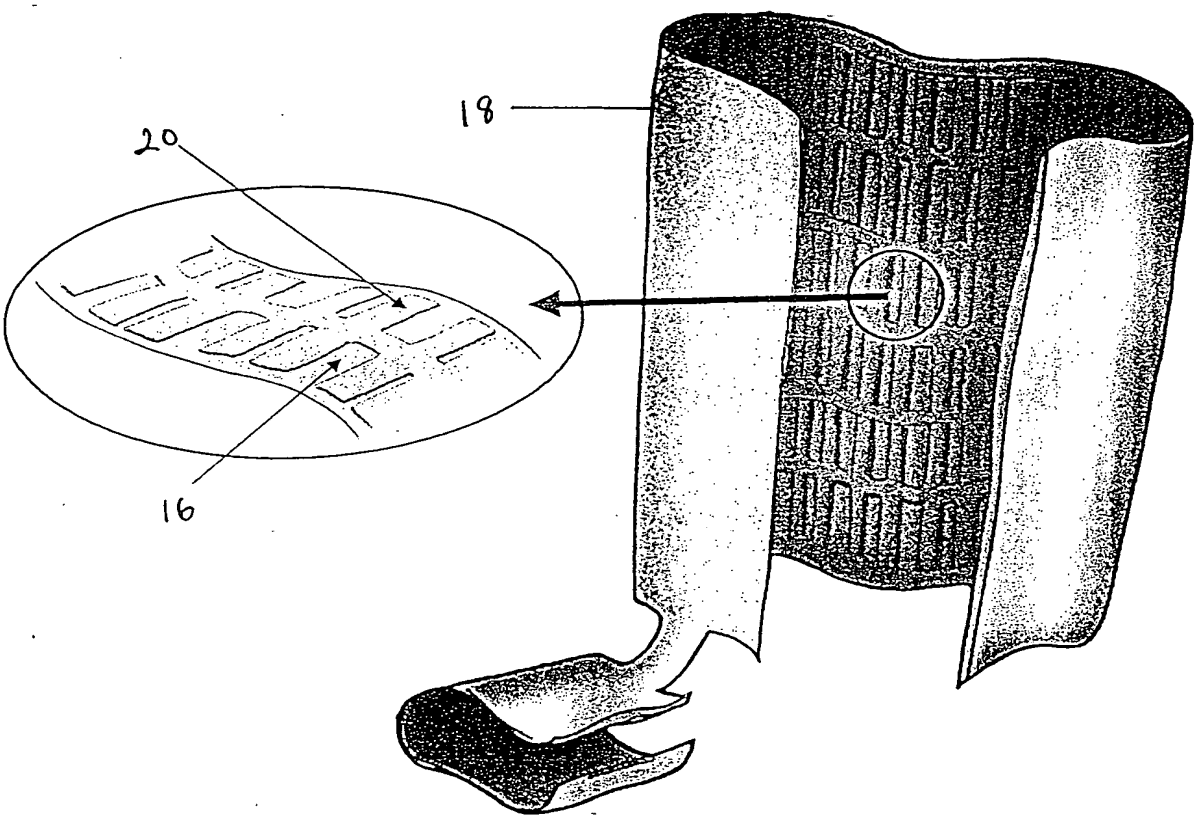

Figure 2

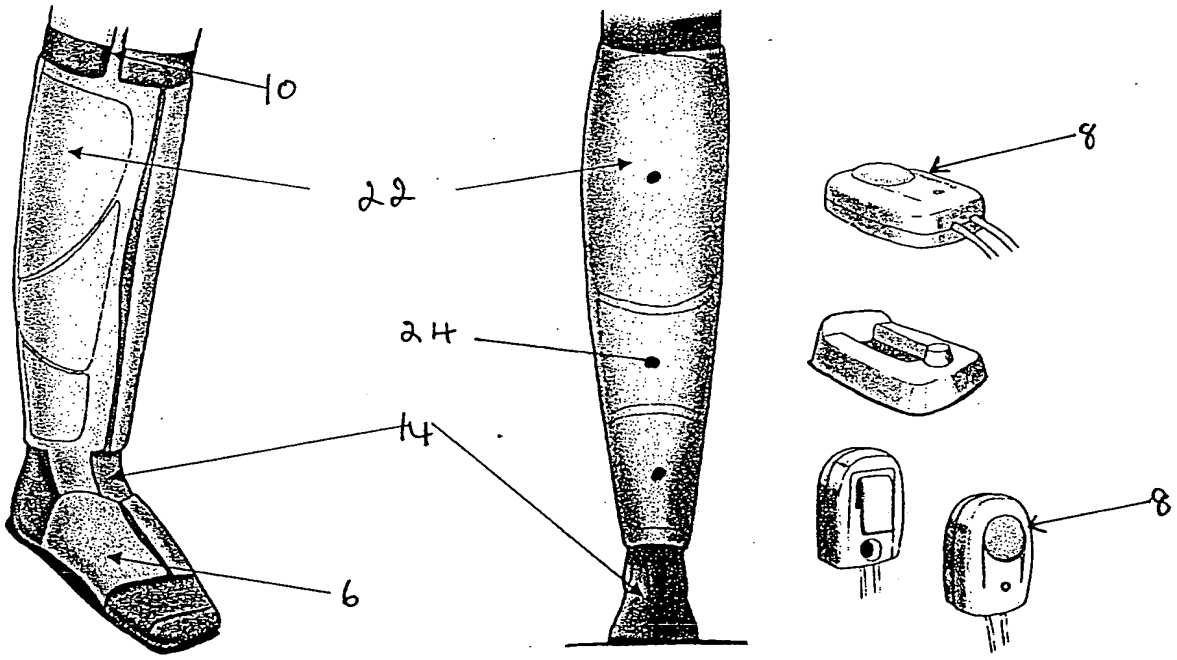

Figure 3